Drug Discovery in China

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Contrary to the public impression that China is the low-cost “world factory,” the Chinese pharmaceutical industry is taking a turn to join the world’s leaders of innovation. In addition to efforts aimed at modernizing the thousand-year-old Chinese traditional medicine, China is also planning major drug discovery programs aided with modern tools such as genomics, proteomics, and medicinal chemistry. Hu Jin Tao, President of China, mentioned “innovation” several times in his most recent state of the Union address to the People’s Congress. He then went on to specify that innovation focused on biomedical research would be one of the key areas for China in the next 10 to 15 years.

The focus on and investment in innovation in healthcare in China applies to both Chinese companies and multinational pharmaceutical companies that operates in China. The Chinese government’s healthcare strategy calls for the support of all companies that are focused on creating innovative medicine, starting from target discovery through entry of healthcare products into the Chinese and World markets. Roche, a pioneer among multinational pharmaceutical companies, agrees with the Chinese government’s view that growth is driven by investing in research and development, and has created the first wholly owned R&D center in China. This important commitment by our company to both Business and Science in the Chinese market could not have occurred without the strong support from Pudong and Shanghai governments. This was culminated
by the visit of Vice-Mayor Zhou Yu Peng to the opening ceremony of our Roche R&D Center, China. Our initial focus in our center will be medicinal chemistry in support of lead generation and lead optimization, with an evolution to include all of the functions necessary to drive these compounds into the clinic. Supplemented by the existing clinical trial team and collaborations throughout the country to support genetic/genomics efforts aimed at target discovery, Roche has set up a true innovation network in China with the research and development center as its hub.

Among the many issues that we addressed in preparation for investing in the Chinese market, one of the key issues was the protection of intellectual property rights. Since its establishment in 1985, the Chinese patent law has undergone two revisions. These have better defined the legal framework concerning the application, evaluation, and approval processes for patents, as well as the enforcement of patents. Today, the Chinese patent law is in compliance with WTO/TRIPS requirements. Since the Chinese government is now focusing considerable funds in support of drug discovery, there is a strong interest to assure strong intellectual property rights protection. In addition, given the increase in both local and global support of the emerging biotech industry in China, intellectual property has become a major factor to consider for all innovation-based domestic and multinational companies. Clearly, the direction that the government has taken to address intellectual property rights has led to greater investments in innovative healthcare.

The discovery of innovative medicines comes from the contributions of both internal and external investments in scientific insight and know-how. Looking externally, we have traditionally established partnerships with key laboratories at universities, clinical research centers, and biotech companies predominantly in the US and Europe. In China, Roche is pursuing a similar strategy because we recognize the strong Chinese scientific community and it emerging clinical and biotech capabilities. While it is our intention to gain access to external innovation in China, we view this as a close partnership whereby we can hopefully provide expertise and know-how to strengthen the innovation capacity of our Chinese partners. The latter aim will be accomplished by our providing seed funding as well as helping to establish a new concept of research and development management and access to the international research and business community.

In order to turn academic discovery into medicine, the government is beginning to emphasize industry participation in major grant applications. The challenge, however, is that world venture capitalists are not yet investing in creating biotech’s firms focused on drug discovery in China. To address this situation, the central government is increasing research-related funding, and—for the first time—it is linking the R&D expenditure by government to the GDP growth of the country (to 2% by 2010). It is estimated
that the research and development funding for the whole country will increase by 20% in 2006.

Talent is another important factor that the Chinese recognize as being a key source for innovation, in which our investment in the market is providing us with a competitive advantage. The number of university graduates in certain fields of science in western countries has and continues to decrease. In contrast, Chinese students consider the study of chemistry and biology as a career opportunity, particularly in the area of synthetic organic chemistry, which traces its foundations back to the 1950s and 1960s. The synthetic chemistry training of young scientists provides a solid foundation for a chemist to become an expert in medicinal chemistry, where chemistry, pharmacology, and biology are closely linked. In addition, highly trained physicians at major teaching hospitals such as Peking Union Medical College Hospital in Beijing and Ruijin Hospital in Shanghai are working to understand the genetic basis of human diseases, and, as such, are contributing to our understanding about therapeutic intervention. Finally, large numbers of Chinese scientists who have developed their academic careers at prestigious universities in the West are now returning to China with the most up-to-date knowledge to help close the cultural, and communication gaps between China and the West.

Traditionally, scientific insights and the transition to translational medicine and/or drug discovery have been limited to the academia. While this operating model is viable, it may not be optimal. Institutions such as the Guangzhou Life Science Institute and the Biochip Center in Shanghai are now experimenting with organizational models that are closer in resemblance to a corporation. This illustrates how the government is supporting the creation of operating models that will help to speed up the translation of insights from research into the development of new medicine. In addition, Chinese hospitals are modernizing and focusing on developing preclinical/clinical trial capabilities that meet international standards. For example, China and Japan are opening a preclinical research center in Beijing so that the results can be utilized in both countries. This step-by-step approach to lift the level of discovery work that may be extended into clinical development represents an important evolution in China.

Unlike India, where the emphasis for innovation is mainly based on entrepreneurship, China places more emphasis on the development of infrastructure to support the development of novel medicines, such as building new hi-tech parks clustered with biotech companies, hospitals, and university institutes. Zhangjiang Hi-Tech Park in Shanghai and similar parks throughout the country offer multinational companies an environment that will foster talent recruitment and that will create close cooperation between the interrelated healthcare organizations.

Hospitals and their networks are the backbone of the Chinese healthcare system. They encounter a huge patient flow: an average doctor in China will see 2–3 times as many patients per day as
in Western countries. The Beijing Tumor Hospital has more than 1400 beds with a bed turnover rate of more than 100%. The efficiency gained in patient recruitment for drug development programs is counterbalanced by lengthy procedures required for the approval and review of clinical trial designs. This makes China less desirable than other markets for conducting international clinical trials. The government is now turning its attention to this issue, and changes in regulatory practices will likely emerge.

In the meantime, all is not lost, as Roche, for example, is currently conducting about 23 clinical trials in China.

During the past five years, the number of domestic pharmaceutical companies in China has decreased from over 6000 to about 4000. This decrease has been driven mainly by consolidation aimed at creating greater critical mass, higher capital, and improved overall capabilities. Even major domestic companies such as Hua Yao (China World Best Group) have reorganized to improve their financial condition. Biotech companies such as Shanghai Genomics, like their peers in the Western world, also face the challenge to reduce their cash burn rate. In this sector, two approaches have been taken to address this concern. First, these companies have implemented a fee-for-service model, which supports the influx of low-value but important operational capital. Second, to drive their internal drug discovery engines, these companies have tapped into the expanding government grant support program. Finally, some companies have decided to focus entirely on the contract research organization business model, which will not drive innovation in the short-term, but could help to enhance the overall experience and know-how of the workforce. This model could support the creation of novel biotech firms in the long run.

Clearly, China is and will continue to be an important healthcare market for multinational and local companies. While the opportunities are great and the government support and vision is clearly focused on providing high-quality healthcare to the people, there are also many challenges. While the opportunities to create strong research and development bases in China are now emerging, we must ensure that issues around intellectual property rights, drug pricing, and drug approvals are addressed in a manner whereby everyone wins. With all of these changes and issues in China moving at such a fast pace, it is only a matter of time before China emerges as a major leader in providing both local and global healthcare.